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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,271	05/04/2001	Steven M. Ruben	PF526	7683

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/19/2002

/o

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. .

09/848,271

Applicant(s)

RUBEN ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,20,21,23,24,26 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 20, 21, 23, 24, 26 and 33-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1, 20, 21, 23, 24, 26 and 33-43 are pending in the instant application. Claims 2-19, 22, 25 and 27-32 have been canceled and claims 33-43 have been added as requested by Applicant in Paper Number 8, filed August 9, 2002.

Restriction Requirement:

2. Applicant's election of Group VI, now represented by claims 24, 26 and 33-43 in paper number 8 filed 8/9/02, with traverse, is acknowledged. The traversal is on the ground(s) that assuming that the groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of the groups would entail a "serious burden", and that no such showing has been made. Applicants assert that the examination and search of Group I would also provide useful information for the claims of Groups II-III, while a search of the claims of Group II would also provide useful information for the claims of Groups IV and VI and a search of Group III would also provide useful information for the claims of Groups V and VII, and that in many if not most publications disclosing a polynucleotide, the authors also routinely include polypeptides encoded thereby, and since the searches for polynucleotides and polypeptides commonly overlap, the search and examination of a polynucleotide and the corresponding polypeptides would not entail a serious burden.

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Applicant's also point out that Groups VI and VII are in the same class and subclass, and have not acquired a separate status in the art as shown by their different classification and would not present a serious burden to search.

This is not found persuasive for Groups VI and VII, because although Groups VI and VII are classified in the same class and subclass, they have different method steps and goals.

Invention VI is directed to a method of diagnosis comprising contacting the polypeptide of Group II with a biological sample, while the invention of Group VII is directed to a method of diagnosis comprising contacting an antibody to the polypeptide of Group II with a biological sample. The polypeptide and antibody would bind to different proteins in the biological sample, and are therefore different methods of diagnosis.

This is not found persuasive for the other groups because consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:.

These criteria were met in the above restriction. Also, a search for antibodies to a protein, for example, would constitute a different search than that of a search for the protein. It is old and well known in the art that antibodies have been generated without having purified protein, and antibodies to one protein may also cross-react with a related protein. As stated in the MPEP § 803, "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02.". Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious, and therefore requires a search and consideration of relevant literature in many different areas of subject

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matter. Thus, the groups require divergent searches, and to search all inventions would be burdensome.

Applicant's species election of Sjogren's syndrome, now represented by claims 26 and 33-43 in paper number 8 filed 8/9/02, with traverse, is acknowledged. The traversal is on the ground(s) that the Examiner has not disclosed any statutory or regulatory basis for the requirement for election of species within the provisionally elected Group VI, and that the members of the Markush groups of the pending claims to provisionally elected Group VI are sufficiently few in number and very closely related, as they are all different autoimmune diseases, so that a search of all of the members may be made without a serious burden.

This is not found persuasive because although many of the different diseases are autoimmune diseases, they have different etiologies and different symptoms, and are distinct separate diseases, each of which would have to be searched and considered separately, which would be a burden because there are at least 80 diseases or disorders listed. Additionally, a disorder such as infertility is not necessarily an autoimmune disorder, but can have many root causes. If the elected species is found allowable, then additional species will be examined.

The Examiner agrees with Applicants that for Group VI, there is no generic claim. However, the species requirement is maintained because claim 26 is a Markush claim, all of the members of which would be a burden to search, as discussed above.

Claims 1, 20, 21 and 23 are withdrawn as being drawn to a non-elected invention.

Election/Restrictions

3. This application contains claims directed to the following patentably distinct species of the claimed invention: antigenic epitopes of the polypeptide of SEQ ID NO: 2 comprising amino acids 9-13, 28-31, 49-52, 105-111 and 133-142. These epitopes are patentably distinct because they each would bind different and patentably distinct antibodies. Further, these would require separate sequence searches.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of antigenic epitope for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 41 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. A telephone call was made to Janet Martineau on Sept. 12, 2002 to request an oral election to the above species election requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



**LORRAINE SPECTOR
PRIMARY EXAMINER**